



USDA Foreign Agricultural Service

# GAIN Report

Global Agriculture Information Network

Template Version 2.09

Voluntary Report - public distribution

**Date:** 4/18/2006

**GAIN Report Number:** E36063

## EU-25

### Trade Policy Monitoring

### The U.S. Food Safety Regulatory System

2006

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**Report Highlights:**

The U.S. food safety system has evolved over a period of 100 years. It has grown to fit the changing dynamic of the U.S. food production market. But as an evolved rather than designed system, there is a level of complexity to the system. The U.S. and the E.U. have some of the safest food supplies in the world. Ensuring food safety is an important role of the U.S. Federal government, and is an example of Federal supremacy over State regulation.

*While this report provides a general overview of the U.S. regulatory system with responsibilities in the area of food safety, readers are referred to the Web sites of the individual USG agencies for detailed information on their respective areas of competence.*

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Includes PSD Changes: No  
Includes Trade Matrix: No  
Unscheduled Report  
Brussels USEU [BE2]  
[E3]

## Food Safety Regulation System in the U.S.

### Executive Summary

The U.S. food safety system has evolved over a period of 100 years. It has grown to fit the changing dynamic of the U.S. food production market. But as an evolved rather than designed system, there is a level of complexity to the system. Four separate agencies have primary responsibility for food safety in the U.S. (Food Safety Inspection Service, Animal and Plant Health Inspection Service, Food and Drug Administration and the Environmental Protection Agency). These agencies ensure the safety, wholesomeness and accuracy of the food supply. Their mission is aided by other federal agencies, as well as a balanced external advisory committee attached to each food safety agency. The promulgation of new regulations is brought forward with openness, fairness and transparency, and this is ensured through the involvement of the Office of Management and Budget. Defined, well-publicized steps ensure that regulations in rule-making are followed, and multiple levels of accountability by regulatory agencies ensures that the ultimate remains improving the safety of the U.S. food supply.

### Introduction

The U.S. and the E.U. have some of the safest food supplies in the world. Ensuring food safety is an important role of the U.S. Federal government, and is an example of Federal supremacy over State regulation. Following the 1906 publication of The Jungle by Upton Sinclair, food safety has been a paramount responsibility of the Federal government. Until that time, state authorities had been responsible for ensuring the safety of the food supply, and these officials were notoriously ineffective and/or corrupt. Following the expose of the meatpacking industry, Congress passed the "Pure Food and Drug Act", which established Federal meat inspection for wholesomeness.

In the 100 years since the Federal government entered meat inspection, there have been periodic reorganizations and realignments, which has allowed the food safety system to maintain its flexibility and adapt to changing business and consumer preferences. Currently, more than 20,000 people work in all sectors of the government ensuring food safety. These range from in-plant inspectors, epidemiologists compiling outbreak data, to scientists searching for ways to improve food safety. The cost of this process each year is in the billions, but the number of lives saved, illnesses spared, and consumer confidence is far greater.

The U.S. system is a product of evolution from within the government, as well as from within the food-producing system. Changes in both sectors have resulted in the regulatory system becoming what it is today. Several key agencies play critical roles in ensuring food safety and safeguarding consumer health and well-being. Interestingly, because of the nature of this long-term evolution, issues that the U.S. regards as food quality issues, are regarding in the E.U. as food safety issues, and vice versa.

### U.S. Regulatory agencies with food safety responsibilities

Food safety agencies are part of the Executive Branch of the U.S. government, but their ability to make rules and regulations has been delegated by the Legislative Branch. In this manner, rule-making agencies are accountable to both branches of government, which are in turn accountable to the general public via election.

In 1997, the President's Food Safety Initiative was enacted which calls for science-based decision making, complete with cost:benefit analysis for all regulatory decisions. This

initiative emphasizes that risk assessments and impact assessments are critical to evaluating the impact of regulations on industry, the economy and consumer safety. The relationships within the food safety agencies was further codified by the Administrative Procedures Act (APA) that established the Office of Management and Budget (OMB) to be the gatekeeper for regulations in the new era of "smart regulation". OMB controls the flow of funds within the federal government, therefore they have control over other agencies for accountability enforcement. The OMB involvement in regulation ensures: that all stakeholders are involved in the regulatory process, that all regulations are prepared with openness, fairness and transparency, and that cost-to-benefit ratios are examined for each proposed regulation. OMB ensures publication of proposed and final regulations in the *Federal Register*, and ensures all regulations were followed prior to the enactment of regulations, and that all stakeholders were actively involved in the development of the regulation.

Food safety is directly overseen by 4 agencies in 2 different cabinet-level departments; each is charged with different mandates and responsibilities (**Table 1**). The Environmental Protection Agency (EPA) is an independent agency that has a highly specialized role in food safety regulation. The EPA controls pesticide use to ensure that they are used appropriately and are not detrimental to the food supply. The Department of Agriculture (USDA) is home to two of the primary food safety agencies, Animal Plant Health Inspection Service (APHIS) and Food Safety Inspection Service (FSIS). Both of these USDA agencies have mandates that include trade considerations. Food security issues are currently overseen by the new Department of Homeland Security (HomeSec).

APHIS is responsible for controlling and combating animal and plant diseases and pests and preventing their importation into the U.S. and for facilitating safe agricultural trade. The APHIS is, at heart, a veterinary agency and is responsible for ensuring national animal care policies are validated. They address sanitary and phytosanitary trade barriers, and ensures that biotechnology products are safe for consumption.

FSIS is responsible for inspections of meat, poultry and eggs, and their mission is to ensure the wholesomeness, safety and accuracy of the food supply. Thus they are the lead agency in meat and poultry safety. FSIS inspectors are in all meat/poultry/egg production plants each day while the plant is in operation, thus FSIS inspectors can certify compliance with production, safety and wholesomeness regulations. Records of foods that test positive for pathogenic bacteria (such as *Salmonella*) are recorded and compiled by FSIS for annual summaries. FSIS also employs compliance officers that enforce food safety during distribution steps.

The other cabinet-level department with food safety responsibilities is the Department of Health and Human Services, home of the Food and Drug Administration (FDA). The FDA has the mission to ensure the safety and accuracy of the food (and drug) supply in areas not controlled by FSIS. Meaning anything other than meat/poultry/eggs is within the bailiwick of FDA, for example imports of coffee are examined by FDA officials. FDA also regulates food and animal feed additives for their safety and purity. The FDA also regulates all veterinary drugs, which gives them a great deal of direct and indirect responsibility to the safety of the food supply.

**Table 1. Alignment of Food Safety Regulatory and Enforcement Agencies**

<b>Agency</b>	<b>Administration</b>	<b>Food Safety Responsibility</b>	<b>Food Safety Mission</b>
Office of Management and Budget (OMB)	Reports directly to the office of the President	Gatekeeper for regulation	Ensures openness, fairness and transparency in regulation proposal, development, and implementation
		Requires cost:benefit analysis for regulations	
		Controls flow of money to all agencies	
		Ensures compliance with Administrative Procedures Act (APA)	
Food Safety and Inspection Service (FSIS)	Department of Agriculture	Inspects meat, dairy and eggs for wholesomeness and safety	Ensures wholesomeness and safety of food supply (meat, dairy and poultry products)
		Verifies labeling accuracy	
		First line of defense against food borne illness	
		Includes trade mandate	
Animal Plant and Health Inspection Service (APHIS)	Department of Agriculture	Protects American agriculture against disease and pests	Ensures outbreaks of plant and animal diseases and pests in the U.S. do not occur
		Ensures animal care standards	
		Includes trade mandate	
Food and Drug Administration (FDA)	Department of Health and Human Services	Regulates safety in foods and drugs not falling under FSIS jurisdiction	Ensures that consumers are not exposed to impure, unsafe, or fraudulently labeled foods or drugs that are not regulated by FSIS
		Regulates food and feed additives for humans and food animals	
		Regulates veterinary drugs and applications in food animals	
Environmental Protection Agency (EPA)	Independent Agency	Regulates pesticide usage	Ensures that pesticides and other pest management techniques are properly used and do not enter the food chain or environment

Other agencies support the food safety mandate of these agencies via scientific, technical and industrial information sharing. Agencies such as Agricultural Research Service, Economic Research Service, Agricultural Marketing Service, Centers for Disease Control and Prevention, Public Health Service, National Institutes of Health, various state and international universities provide scientific input on food safety impacts on society. Trade, industry and consumer groups (such as Consumers for Science in the Public Interest) provide input on technical issues as well as economic and social impacts. Additionally, food-producing companies and trade organizations in the U.S. have agreed that food safety is NOT a

competitive issue. Improvements in food safety are shared amongst all companies freely, improving food safety is not a proprietary function.

All entities involved with food safety mandates take their role in protecting the consumer very seriously. These entities communicate with each other through informal technical channels, as well as formal channels during regulation preparation and evaluation.

### **How are food safety regulations enacted in the U.S.?**

Science-based regulations are critical for maintaining the safety of the nation's food supply. The federal agencies responsible for food safety in the United States promulgate regulations to ensure and promote the safety of the foods they regulate.

The food safety agencies are part of the Executive Branch of the U.S. Government and implement the laws enacted by Congress. The laws, or statutes, enacted by Congress form the basis for these agencies' regulatory programs. Regulations promulgated by the agencies must be based on and consistent with these statutes.

Further, there other statutes, Executive Orders by the President, and instructions from the Office of Management and Budget (OMB) that affect rulemaking. For example, one of the requirements agencies must meet in rulemaking is that all data used to underpin significant regulations must be adequately peer reviewed according to OMB standards. Rulings by Federal courts also affect the agencies' rulemaking.

Advisory committees comprised of scientific, technical, and other experts offer advice to the agencies. Agencies consult the advisory committees regarding food safety issues and policies which often result in further rulemaking.

Anyone may petition the agencies to either rescind or revise a regulation, or promulgate a new regulation. In addition, agencies periodically hold public meetings to explore and provide a public forum on important food safety issues before the agency proceeds with rulemaking.

Sometimes an agency will give the public a "heads up" by publishing an Advanced Notice of Proposed Rulemaking (ANPR) in the Federal Register. The ANPR outlines the need for the rule, discusses the issues related to the proposed rulemaking, including its potential economic and social impact, and solicits public comment.

When an agency decides to proceed with rulemaking, it usually develops a workplan for a proposed rule that is submitted to OMB to receive a designation. OMB designates proposed rules as Major, Economically Significant, Significant, or Non-significant. Rules, other than non-significant ones, must be first cleared by OMB before they are published in the Federal Register.

As a part of rulemaking, the agency prepares a regulatory impact analysis, which includes a cost-benefit analysis that weighs the anticipated economic costs with the expected economic and social benefits, including health benefits, of the rule.

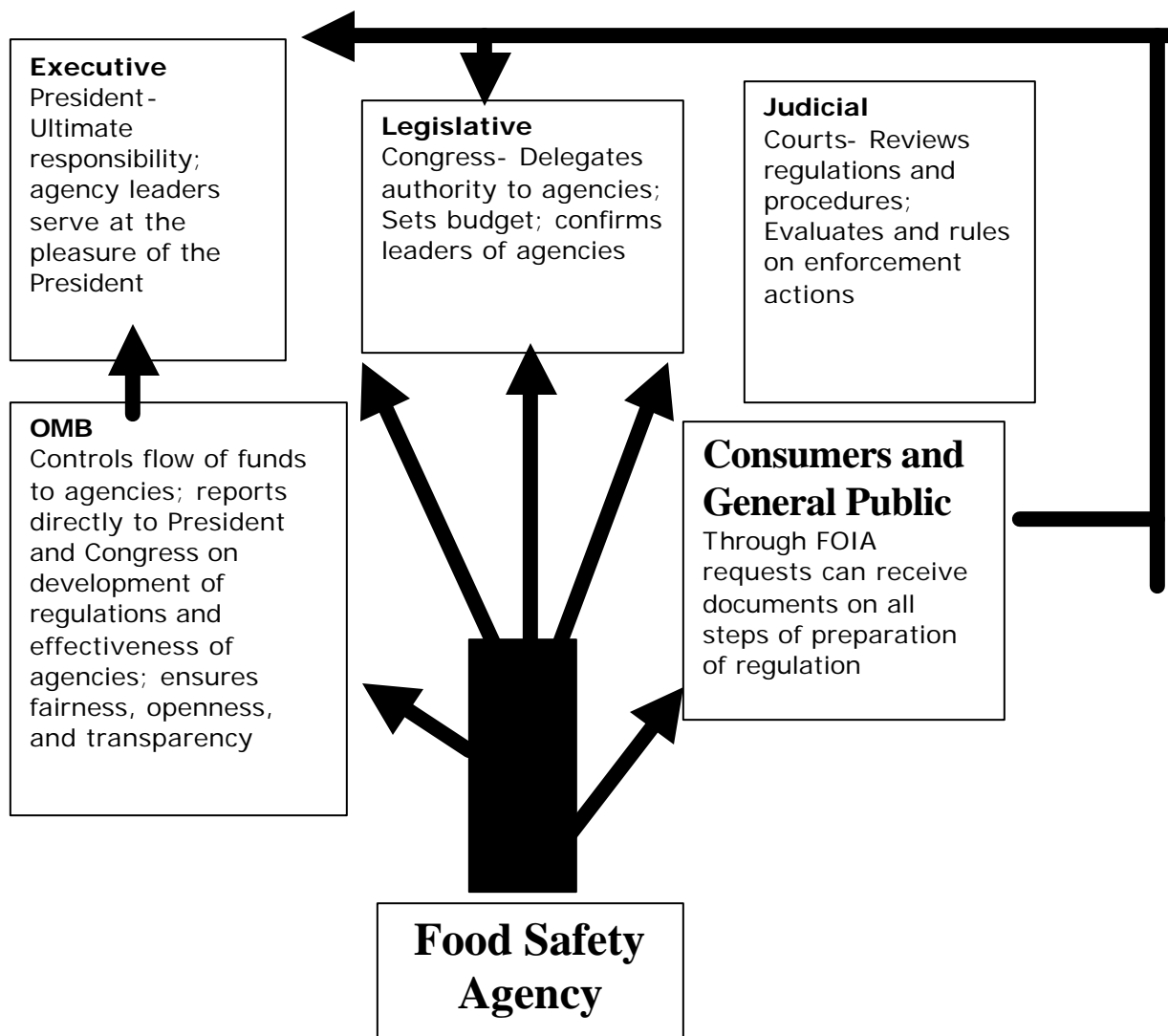
After receiving clearance from OMB, the agency publishes the proposed rule in the Federal Register which allots a time (usually 60 days) for the public to provide comment on the proposal.

After receiving comments from the public, including any data relevant to the proposed rule, the agency reviews and analyzes all the comments. In the final rule, which also must be cleared by OMB, the agency lists and responds to all the comments submitted by the public.

The final rule may differ even significantly from the proposed rule based on the comments and additional data that the agency may receive.

### Accountability

One of the critical features of the food safety system is the multiple layers of accountability built into the system (Figure 1).



Following this process, all residents of the U.S. are able to obtain nearly all information pertaining to the development of a rule or regulation via the submission of a "Freedom of Information Act" (FOIA) request. FOIA ensures that all rules were followed in an open and transparent manner by making nearly all documentation available to the general public. The only information that is withheld is sensitive or confidential to national security, or is proprietary information.

### Other agencies involved in food safety and food quality

Because some of what the U.S. views as food quality issues are regarded by trading partners as food safety issues regulation of the food supply does not just include the above

mentioned food safety agencies. USDA includes several other agencies involved in regulation of the food supply as well. The Agricultural Marketing Service (AMS) oversees marketing agreements, improves logistics of transportation and marketing of foods, administers the pesticide and hormone-free record-keeping programs, and provides standardization, grading and market news for the various commodities. The Plant Variety Protection Office of AMS issues certificate of protection for new varieties of sexually reproduced plants. AMS also enforces the Perishable Agricultural Commodities Act and the Federal Seed Act. The Grain Inspection, Packers and Stockyards Administration (GIPSA) facilitates the marketing of livestock, poultry, meat, cereals, oilseeds, and related agricultural products, and promotes fair and competitive trading practices. The Food, Nutrition and Consumer Services Agency provides food relief for underprivileged citizens, and is a large purchaser of bulk foods. The Foreign Agricultural Service (FAS) has the primary responsibility for USDA's international activities including market development, trade agreements and negotiations, and the collection and analysis of export/import statistics and market information. It also administers USDA's export credit guarantee and food aid programs, and helps increase income and food availability in developing nations by mobilizing expertise for agriculturally led economic growth. FAS also provides linkages for producers to global resources and international organizations and serves as a central point of inquiry on agricultural trade matters.

Wine and beer are regulated by the Alcohol and Tobacco Tax Trade Bureau (Dept. of Treasury) and regulations are enforced by the Bureau of Alcohol, Tobacco, Firearms and Explosives (BATF; Dept. of Justice). The safety of wine and beer are regulated by the FDA, but BATF can inspect facilities that produce beer and wine for tax and safety purposes as part of their law enforcement mandate. Transportation of foods and feeds fall under the aegis of the Department of Transportation in some situations, which complicates jurisdictional issues. The Department of Labor ensures the health and safety of workers in the food production industry. The U.S. marine resources are managed through the National Oceanic and Atmospheric Administration (NOAA). The scientists with NOAA Fisheries focus on sustaining marine resources. Food security against non-natural threats is coordinated by the newest cabinet-level department, Homeland Security.

## Conclusions

The food supply of the U.S. and EU is extremely safe, and is improving still. However, food borne illnesses still occur too frequently. The science-based food safety system of the U.S. government is a flexible system that is still evolving after 100 years of existence. Food safety agencies work together to ensure that the food supply remains safe and wholesome. Different food safety agencies have specific responsibilities and mandates that include inspection, trade, protection, and regulation.

The system of making regulations is carefully controlled to ensure fairness, openness and transparency. This process also actively encourages involvement from the regulated industry and consumers. This openness allows the evidence to be examined scientifically and the risks to be addressed evaluated carefully and logically. Inclusion of cost-to-benefit analyses allows an objective point of view about the feasibility of imposing regulations. By imposing a web of accountability the openness and transparency of the rule-making process is ensured.

Additional information on U.S. regulatory agencies with responsibilities in the area of food safety can be found on the Internet; please see the Web sites of [OMB](#), [FSIS](#), [APHIS](#), [FDA](#), [EPA](#), [AMS](#), [GIPSA](#), [FAS](#), [BATF](#), and [NOAA](#).

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